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PATENT APPLICATION
Docket No. 16096.5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re application of | | ) |
| | Khemani et al. | ) |
| Serial No. | 10/087,256 | ) Art Unit |
| | | ) 1711 |
| Confirmation No. | 4244 | ) |
| Filed: | March 1, 2002 | ) |
| For: | BIODEGRADABLE POLYMER BLENDS FOR USE IN MAKING FILMS, SHEETS AND OTHER ARTICLES OF MANUFACTURE | ) |
| Examiner: | Ana Lucrecia Woodward | ) |
| Customer No.: | 022913 | |

**DECLARATION OF HARALD SCHMIDT**

**UNDER 37 C.F.R. § 1.131**

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Harald Schmidt, hereby declare as follows:

1. I am one of the co-inventors of the subject matter disclosed and claimed in the above-identified application ("Subject Application"), and I am personally knowledgeable of the facts stated herein.

2. I am also one of the co-inventors named in U.S. Patent No. 6,096,809 to Lorcks et al.

3. Both the Subject Application and Lorcks et al. are assigned to bio-tec Biologische Naturverpackungen GmbH & Co., KG. ("Biotec"), which is located at Werner-Heinsenberg-Sr. 32, Emmerich, Germany 46446.

4. I am currently, and at the time of the invention was, Vice President in charge of manufacturing thermoplastic biodegradable polymers, and am therefore an expert with regard to at least those biodegradable polymers with which I have worked.

5. I am familiar with the thermoplastically processable starch blends disclosed in Lorcks et al. because I have manufactured them myself.

6. The "thermoplastic starch" disclosed in Lorcks et al. is made according to PCT/WO90/05161, which corresponds to U.S. Patent No. 5,362,777, and includes a substantial quantity of a high boiling liquid plasticizer such as glycerin, typically 10%-40% by combined weight of the starch and plasticizer. Lorcks et al., col. 1, line 62 – col. 2, line 6.

7. U.S. Patent No. 5,362,777 to Tomka is also assigned to Biotec and discloses and claims a "thermoplastically processable starch" ("TPS") composition that is "substantially water free" and a method of manufacturing such composition. Tomka, col. 13, line 2; col. 14, line 40.

8. During prosecution of Tomka, the term "substantially water free" was successfully argued to distinguish over a "destructurized starch composition" containing 5-30% water described in a patent referred to as the "Lay reference". The fact that the USPTO issued claims 1 and 20 of Tomka indicates that the term "substantially water free" was understood to mean some amount of water less than 5% so as to distinguish over the Lay reference. This term was ultimately held to satisfy the definiteness requirement of 35 U.S.C. § 112, second paragraph.

9. During litigation, the issue of the meaning of the term "substantially water free" was hotly contested. The trial court held this term to mean less than 5% water based on arguments made to distinguish over the Lay reference. *Biotec Biologische v. Biocorp*, 249 F.3d 1341, 1346 (Fed. Cir. 2001) (referring to the trial court's decision below). On appeal, the Federal Circuit confirmed this interpretation. *Id.* at 1347.

10. It is my opinion that the phrase "substantially free of high boiling liquid plasticizers" is likewise definite and means that the optional thermoplastic starch component is either entirely free of high boiling liquid plasticizers or includes less than the amount required to form a thermoplastic starch melt in the absence of water. As is well-known to those of skill in the art of thermoplastic starch, the melting temperature of starch approaches or exceeds the decomposition temperature of starch. For that reason it is impossible to place native starch granules in a pan and cause them to melt in the absence of water or some other plasticizer. Heating starch in the absence of a plasticizer will cause it to burn or decompose.

11. In the 1980's, several attempts were made to manufacture "destructurized starch" ("DSS") using 5-30% water to form a thermoplastic starch melt, with the Lay reference of Warner-Lambert being among the most prominent DSS patents of the day. Because the melting point of starch exceeds the boiling point of water, destructurized starch can only be made using a closed vessel (*e.g.*, a pressure cooker). The tendency of water to vaporize during formation made the production of DSS difficult and economically non-viable.

12. In an effort to avoid the negative effects of superheated and/or vaporizing water, Tomka taught that water (*e.g.*, the natural water content of starch) could be replaced with one or more high boiling liquid plasticizers such as glycerin to lower the melting temperature of starch to below its decomposition temperature. Tomka, col. 13, lines 1-8. Such high boiling plasticizers solved the problem of the high volatility of water during processing because they have a vapor pressure of less than 1 bar at the melting temperature of the thermoplastic starch composition. *Id.* at col. 13, lines 10-12.

13. Tomka discloses and claims thermoplastic starch compositions in which the high boiling liquid plasticizer or "additive" is included in an amount of at least 5% by combined weight of the starch and additive, with 10-30% being preferred. *Id.* at col. 6, lines 54-59; col. 13, lines 3-6. Tomka further teaches:

> Depending on the properties desired for the shaped body to be produced, such as thermal and mechanical properties in particular, about 10 to 35% plasticizer or additive respectively is preferably added to the native starch, <u>the water of the starch being replaced by the addition of the additives or removed by drying</u>.

*Id.* at col. 6, lines 54-59 (emphasis added).

14. In short, it is my understanding, based on my experience in manufacturing thermoplastic starch compositions, that native starch cannot be melted in the absence of either at least 5% water, or at least 5% of a high boiling liquid plasticizer or "additive" in the absence of at least 5% water. However, we found that using high boiling liquid plasticizers such as glycerin may not be desirable in the case where a sheet or film is intended to contact food, since the plasticizer can diffuse out of the polymer matrix and into the food.

15. As taught in the present application, native starch granules are initially melted using water, which is then removed by evaporation, after the starch melt has been blended with one or more synthetic biodegradable polymers:

> Preferred thermoplastic starch polymers for use in making food wraps may advantageously utilize the natural water content of native starch granules to initially break down the granular structure and melt the native starch. Thereafter, the melted starch can be blended with one or more synthetic biopolymers, and the mixture dried by venting, in order to yield a final polymer blend.

Application, pp. 9-10, ¶ [0023]; *see* pp. 33-34, ¶¶ [0092]-[0094].

16. It is my opinion that the term "substantially free of high boiling liquid plasticizers" would be understood by one of skill in the art to mean less than the threshold amount of such plasticizers (*i.e.*, 5% by combined weight of starch and plasticizer) required to form a thermoplastic starch melt in the absence of at least 5% water.

17. In contrast, Lorcks et al. does not disclose thermoplastic starch manufactured in this manner. Instead, Lorcks et al. teaches the use of TPS that includes 10-40% of a high boiling liquid plasticizer:

> Because of the poor suitability of native starch as an "engineering plastic" it is proposed according to the invention to use so-called thermoplastic starch, as is proposed, for example, in PCT/WO90/05161. This thermoplastic starch is obtained by processing native starch in the melt, by means of a plasticizing or swelling agent, to a homogeneous mass, where the proportion of swelling or plasticizing agent can as a rule amount to between <u>10 and about 40%</u>, based on the overall weight of the mixture.

Lorcks et al., col. 1, line 62 – col. 2, line 6 (emphasis added).

18. In order to obtain thermoplastic starch that is substantially free of high boiling liquid plasticizers, we had to deviate from the teachings of Lorcks et al., which requires 10-40% by weight of a plasticizer. That is because Lorcks et al. specifically teaches that the natural water content of native starch is replaced with a plasticizer such as glycerin, with the water being preferably removed by predrying the starch.

19. As I stated above, the term "substantially free of high boiling liquid plasticizers" would be understood by one of skill in the art to either include no plasticizer or less than the

threshold amount of plasticizer required to form a starch melt from native starch in absence of at least 5% water. It is therefore my opinion that the term "thermoplastic starch that is substantially free of high boiling liquid plasticizers" or "glycerin" cannot be obtained following the teachings of Loreks et al.

20. The preferred "soft synthetic thermoplastic biodegradable polymer" used in the inventive blends is an aliphatic-aromatic copolyester, such as ECOFLEX, manufactured by BASF, or EASTARBIO, manufactured by Eastman Chemical. Such polymers have far better processability when blended with a "stiff" biodegradable polymer compared to purely aliphatic polyesters such as polycaprolactone.

21. ECOFLEX and EASTARBIO differ substantially from other types of aliphatic-aromatic copolyesters such as BIOMAX due to their low glass transition temperature (Tg). BIOMAX is an aliphatic-aromatic copolyester having a Tg of 70°C, making it a "stiff" polymer. In contrast, ECOFLEX and EASTARBIO are formulated in such a manner as to have an extremely low Tg (*i.e.*, -33°C), which greatly increases the elongation and flexibility of films and sheets made from blends of stiff and soft polyers that include ECOFLEX or EASTARBIO.

22. The superior results obtained by using an aliphatic-aromatic copolyester having a Tg of less than about 0°C is further evidenced by the fact that ECOFLEX is mentioned prominently in the present application as the preferred "soft" biodegradable polymer and that is has been and remains our most preferred "soft" synthetic biodegradable polymer utilized in most of the commercial blends of Biotec having "hard" and "soft" polymers.

I declare further that all statements made herein of my own knowledge are true and that all statements are made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at Emmerich, Germany, this 20th day of December 2005.

Harald Schmidt
Co-inventor

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